

SOP 21

REPORTING OF RESEARCH EVENTS TO FACILITY OVERSIGHT COMMITTEES AND THE OFFICE OF RESEARCH OVERSIGHT

- 1.0 **PURPOSE AND SCOPE:** This SOP specifies the requirements for reporting certain research events to local oversight committees and to the Office of Research Oversight (ORO). This policy provides timelines and identifies events in research that must be reported to the Office of Research Oversight Southern Regional Office (SRO) and/or Office of Research Oversight Central Office with a copy to the VISN Director.
- 2.0 **DEFINITIONS**
- 2.1 **Administrative Hold.** An administrative hold is a voluntary interruption of research enrollments and ongoing research activities by an appropriate facility official, research investigator, or sponsor (including the VHA ORD when ORD is the sponsor).
- 2.2 **Adverse Event (AE) in Research.** An AE in research is defined for purposes of this SOP as any untoward occurrence (physical, psychological, social, or economic) in a human subject participating in research. An AE in research can be any unfavorable or unintended event including abnormal laboratory finding, symptom, disease, or death associated with the research or the use of a medical investigational test article. An AE in research may occur even in the absence of any error or protocol deviation, and does not necessarily have to be caused by any identifiable aspect of the research.
- 2.3 **Animal (Laboratory Animal).** A laboratory animal is a live (non-human) vertebrate used or intended for use in research, research training, experimentation, or biological testing, or for a related purpose.
- 2.4 **Assurance (Assurance of Compliance).** An Assurance of Compliance is a written commitment to a Federal department or agency to ensure compliance with applicable requirements. For example, the participation of human subjects in VA research requires a Federalwide Assurance (FWA) for the Protection of Human Subjects, and the participation of laboratory animals in VA research requires a Public Health Service (PHS) Animal Welfare Assurance.
- 2.5 **Continuing Noncompliance.** Continuing noncompliance is persistent or repeated failure, either in the past or extending into the present, to satisfy VA or other Federal research requirements
- 2.6 **Human Subject Research.** Human research is any research involving any of the following:
- 2.6.1 One or more human subject(s).
 - 2.6.2 Data containing identifiable private information about one or more living individuals.

2.6.3 One or more human biological specimen(s).

2.7 **Human Subject.** A human subject is a living individual about whom an investigator is conducting research obtains:

2.7.1 Data through intervention or interaction with the individual; **NOTE:** *Private information is considered individually identifiable when it can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. Private information that cannot be so linked by the investigators is not considered individually identifiable.* and/or

2.7.2 Identifiable private information.

2.8 **Institutional Animal Care and Use Committee (IACUC).** An IACUC is a committee formally designated by an institution to ensure compliance with animal research regulations and guidelines and maintenance of an Animal Care and Use Program (ACUP).

2.9 **Institutional Official (IO).** The IO is the individual legally authorized as Signatory Official to commit an institution to an Assurance. The Facility Director, or equivalent, serves as IO for VA research facilities that conduct research.

2.10 **Institutional Review Board (IRB).** An IRB is a board, committee, or other group formally designated by an institution to review, approve, require modification in, disapprove, and conduct continuing oversight of human research.

2.11 **Investigator.** An investigator is any individual who conducts research, including, but not limited to: the Principal Investigator, co-investigator, local site investigator, etc. A VA investigator must uphold professional and ethical standards and practices and adhere to all applicable VA and other Federal requirements, and to the applicable VA facility's policies and procedures.

2.12 **Memorandum of Understanding (MOU).** An MOU is a formal written agreement entered into by and between (or among) two (or more) parties to set forth the terms, conditions, and understandings of the parties with respect to a specific activity. The MOU helps to ensure that all parties maintain compliant programs of research while defining responsibilities and reducing unnecessary duplication of effort and services.

2.13 **Principal Investigator (PI).** A PI is a qualified person designated by an applicant institution to direct a research project or program. The PI oversees scientific, technical, and the day-to-day management of the research. In the event of an investigation conducted by a team of individuals, the PI is the responsible leader of that team.

2.14 **Research.** Research is a systematic investigation designed to develop or contribute to generalizable knowledge.

- 2.15 **Research and Development (R&D) Committee.** The R&D Committee is a committee responsible, through the Chief of Staff (COS) to the VA Facility Director, for oversight of the facility's research program and for maintenance of high standards throughout that program.
- 2.16 **Research Compliance Officer (RCO).** The RCO is an individual whose primary responsibility is auditing and reviewing research projects relative to requirements for the protection of human subjects, laboratory animal welfare, research safety, and other areas under the jurisdiction of and specified by the ORO. A VA research facility's lead RCO must report directly to the Facility Director.
- 2.17 **Research Impropriety.** For purposes of this SOP the term "research impropriety" refers to noncompliance with the laws, regulations, or policies regarding human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, research misconduct, and other matters as the Under Secretary for Health may assign. Research impropriety does not encompass improper procedures or conduct in areas outside of the jurisdiction of ORO, such as: waste, fraud, abuse, or fiscal mismanagement.
- 2.18 **Research Misconduct.** Research misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- 2.19 **Serious Noncompliance.** Serious noncompliance is the failure to adhere to the laws, regulations, or policies governing human research that may reasonably be regarded as:
- 2.19.1 Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others; or
- 2.19.2 Substantively compromising the effectiveness of a facility's human research protection or human research oversight programs.
- 2.20 **Serious AE (SAE) or Serious Problem.** For the purposes of this SOP:
- 2.20.1 An SAE in research is an AE in human research that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect. An AE is also considered serious when medical, surgical, behavioral, social, or other intervention is needed to prevent such an outcome.
- 2.20.2 A serious problem in human research is one that results in:
- (a) Substantive harm or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others; or
- (b) Substantively compromising the effectiveness of a facility's human research protection or human research oversight programs.

2.20.3 An AE or problem in research is also considered serious when medical, surgical, behavioral, social, or other intervention is needed to prevent preceding subparagraphs.

2.21 Suspension or Termination of Research. For purposes of this SOP:

2.21.1 Suspension refers to a temporary interruption in the enrollment of new subjects, activities involving previously enrolled subjects, or other ongoing research activities.

2.21.2 Termination refers to a permanent halt in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities.

2.21.3 The terms “suspension” and “termination” apply to interruptions related to concerns regarding:

(a) The safety, rights, or welfare of human research subjects, research investigators, research staff, or others; or

(b) The safety or welfare of laboratory animals.

2.21.4 Suspensions and terminations do not include:

(a) Interruptions in human research resulting solely from the expiration of the IRB approval period.

(b) “Administrative holds” or other actions initiated voluntarily by an appropriate facility official, research investigator, or sponsor for reasons other than those described in preceding subparagraph 2.21.3.

2.22 Unanticipated or Unexpected Problem or AE. The terms “unanticipated” and “unexpected” refer to an event or problem in VA research that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population.

2.23 VA Research. VA research is research conducted by VA investigators (serving on compensated, work without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointments) while on VA time, utilizing VA resources (e.g., equipment), or on VA property (including space leased to or used by VA). The research may be funded by VA, by other sponsors, or be unfunded.

3.0 REPORTING REQUIREMENTS: The VHA facility must report to the ORO SRO and/or ORO CO:

3.1 Human Research

3.1.1 Problems in VA Research. Problems involving risks to subjects or others that are unanticipated and serious and related to the research (e.g., work-related injuries requiring more than minor medical intervention or extended surveillance or leading to serious

complications or death; interruptions related to safety, rights, or welfare of subjects or others; VA National Pharmacy Benefits Management (PBM), Data Monitoring Committee (DMC) or sponsor safety reports).

(a) Within 5 business days of becoming aware of any serious unanticipated problem involving risks to subjects or others in VA research, members of the VA research community are required to ensure that the problem has been reported in writing to the IRB.

(b) Within 5 business days after a report of a serious unanticipated problem involving risks to subjects or others, or of a local unanticipated SAE, the convened IRB or a qualified IRB member-reviewer must determine and document whether or not the reported incident was serious and unanticipated and related to the research.

(c) The facility Director must notify ORO in writing within 5 business days after being informed of these events.

(1) The facility Director's written report is required regardless of whether disposition of the event or other issue has been resolved at the time of the report.

(2) Follow-up reports detailing any additional findings and appropriate remedial actions must be provided to the relevant ORO regional office at intervals and in a manner specified by that office.

(3) Copies of any ORO compliance reports regarding the research program must be reported to the associate chief of staff for research, Research and Development Committee, any relevant research review committee(s), and the research compliance officer in a timely fashion.

3.1.2 AEs. Any AE in VA research that is determined to be serious (i.e., an SAE) and unanticipated and related, or possibly related, to the research.

(a) Within 5 business days of becoming aware of any local (i.e., occurring in the reporting individual's own facility) unanticipated SAE in VA research, members of the VA research community are required to ensure that the SAE has been reported in writing to the IRB. *NOTE: This requirement is in addition to other applicable reporting requirements (e.g., reporting to the sponsor under FDA requirements). The unfounded classification of an SAE as "anticipated" constitutes serious noncompliance.*

(b) If the convened IRB or the qualified IRB member-reviewer determines that the problem or event is serious and unanticipated and related to the research, the IRB Chair or designee must report the problem or event directly (without intermediaries) to the facility Director within 5 business days after the determination.

(c) The facility Director must notify ORO in writing within 5 business days after being informed of these events.

(1) The facility Director's written report is required regardless of whether disposition of the event or other issue has been resolved at the time of the report.

(2) Follow-up reports detailing any additional findings and appropriate remedial actions must be provided to the relevant ORO regional office at intervals and in a manner specified by that office.

(3) Copies of any ORO compliance reports regarding the research program must be reported to the associate chief of staff for research, Research and Development Committee, any relevant research review committee(s), and the research compliance officer in a timely fashion.

3.1.3 Apparent Serious or Continuing Noncompliance. Examples of apparent serious or continuing noncompliance that must be reported to the IRB within 5 business days include, but are not limited to: (1) Any finding of noncompliance with human research requirements by any VA office (other than ORO) or any other Federal or state entity (e.g., FDA). Subsequent reports to ORO based on findings made by entities external to the facility must include a copy of the official findings. (2) Initiation of VA human subject research, regardless of level of risk or number of subjects, without written notification from the ACOS for Research that the project may begin. (3) Initiation of VA human subject research, regardless of level of risk or number of subjects, without approval by the IRB. (Note: Additional examples can be found in VHA Handbook 1058.01).

(a) Within 5 business days of becoming aware of any apparent serious or continuing noncompliance with applicable human research protection requirements (e.g., 38 CFR 16, VHA Handbook 1200.05, FDA regulations), members of the VA research community are required to ensure that the apparent noncompliance has been reported in writing to the IRB.

(b) Within 5 business days of identifying apparent serious or continuing noncompliance based on an informed consent audit, regulatory audit, or other systematic audit of VA research, an RCO must report the apparent noncompliance directly (without intermediaries) to the facility Director.

(c) The RCO will simultaneously report apparent noncompliance to the ACOS for Research, the R&D Committee and the IRB.

(d) Within 5 business days of becoming aware of any apparent serious or continuing noncompliance with applicable human research protection requirements an initial report of apparent serious or continuing noncompliance based on a research compliance officer consent document audit, research

compliance officer regulatory audit, or other systematic research compliance officer audit is required regardless of whether disposition of the matter has been resolved at the time of the report.

(1) Unless the non-compliance has already been reported within five business days after receiving such notification, the medical center director must report the determination to:

- o The appropriate Office of Research Oversight Regional Office.
- o The VISN Director.
- o Office of Research Development.

(2) An initial report of an IRB determination that serious non-compliance or continuing non-compliance occurred is required, even where the determination is preliminary or disposition of the matter has not been resolved at the time of the report.

(3) Remedial actions involving a specific study or research team must be completed within 90-120 days after the IRB's determination.

(4) Remedial actions involving programmatic non-compliance must be completed within 120-180 days after the IRB's determination, unless remediation requires substantial renovation, fiscal expenditure, hiring, or legal negotiations.

(5) Members of the VA research community must report possible serious or continuing non-compliance with VA or other federal requirements related to human research or with IRB requirements or determinations to the associate chief of staff for research and development and the IRB within five business days after becoming aware of it.

(d) The IRB must review any report of apparent serious or continuing noncompliance, at its next convened meeting. *NOTE: The IRB Chair, or designee, needs to consult the ORO SRO if the significance of a reported event is not clear.*

(e) The facility Director must notify ORO in writing within 5 business days after being informed of these events.

(1) The facility Director's written report is required regardless of whether disposition of the event or other issue has been resolved at the time of the report.

(2) Follow-up reports detailing any additional findings and appropriate remedial actions must be provided to the relevant ORO regional office at intervals and in a manner specified by that office.

(3) Copies of any ORO compliance reports regarding the research program must be reported to the associate chief of staff for research, Research and

Development Committee, any relevant research review committee(s), and the research compliance officer in a timely fashion.

(4) The facility will also report apparent and/or serious or continuing noncompliance to:

- The Office of Research and Development, if VA-funded.
- The Regional Office of Research Oversight.
- The VA Privacy Office, when the report involves unauthorized use, loss, or disclosure of individually identifiable patient information.
- The VHA Information Security Officer when the report involves violations of VA information security requirements.
- OHRP in all cases.
- FDA when the research is subject to FDA regulations.

3.1.4. **Examples of apparent continuing noncompliance** that must be reported to the IRB within 5 business days include, but are not limited to: (1) Failure to implement IRB-required changes to an on-going protocol within the time period specified by the IRB. (2) Deficiencies in informed consent or HIPAA authorization procedures or documentation for ten or more subjects (e.g., outdated informed consent or HIPAA content; lack of required informed consent elements; lack of information required by VA; lack of signature of individual obtaining consent). (3) Failure to maintain documentation required by the IRB or by the IRB-approved protocol for ten or more subjects (e.g., inadequate medical record documentation where required; inadequate case report forms where required). (Note: Additional examples can be found in VHA Handbook 1058.01).

(a) Within 5 business days of becoming aware of any apparent serious or continuing noncompliance with applicable human research protection requirements (e.g., 38 CFR 16, VHA Handbook 1200.05, FDA regulations), members of the VA research community are required to ensure that the apparent noncompliance has been reported in writing to the IRB.

(b) Within 5 business days of identifying apparent serious or continuing noncompliance based on an informed consent audit, regulatory audit, or other systematic audit of VA research, an RCO must report the apparent noncompliance directly (without intermediaries) to the facility Director.

(c) The IRB must review any report of apparent serious or continuing noncompliance at its next convened meeting. *NOTE: The IRB Chair, or designee, needs to consult the ORO RO if the significance of a reported event is not clear.*

(d) The facility Director must notify ORO in writing within 5 business days after being informed of these events.

(1) The facility Director's written report is required regardless of whether disposition of the event or other issue has been resolved at the time of the report.

(2) Follow-up reports detailing any additional findings and appropriate remedial actions must be provided to the relevant ORO regional office at intervals and in a manner specified by that office.

(3) Copies of any ORO compliance reports regarding the research program must be reported to the associate chief of staff for research, Research and Development Committee, any relevant research review committee(s), and the research compliance officer in a timely fashion.

3.1.5 Terminations or Suspensions of IRB Approval. Termination or suspension of IRB approval of research that are related to concerns about the safety, rights, or welfare of human research subjects, research staff, or others.

(a) Any termination or suspension of research (e.g., by the IRB or other research review committee, or by the ACOS for Research or other facility official) related to concerns about the safety, rights, or welfare of human research subjects, research staff, or others must be reported directly (without intermediaries) to the facility Director within 5 business days after the termination or suspension occurs.

3.1.6 Assurance Changes. Any change in the facility's FWA, or other human research Assurance must be submitted to ORO Central Office prior to submission to OHRP and in accordance with VHA Handbook 1058.03.

(a) Designated personnel will initiate changes to the FWA and will forward the revised FWA and VA Addendum to the Facility Director and VISN Director for review, approval and signature.

(b) The revised FWA (including VA Addendum) will be forwarded to designated personnel in ORO Central Office for review, approval and signature.

(c) ORO Central Office Personnel will forward the revised FWA to OHRP.

3.1.7 IRB Changes. The proposed addition or removal of the IRB(s) of record designated in a facility's FWA must be submitted to ORO Central Office prior to submission to OHRP and in accordance with VHA Handbook 1058.03. Any change in IRB membership rosters must be reported to the appropriate ORO Central Office Program Officer within 30 days of the change of membership, in accordance with VHA Handbook 1058.03.

(a) Before transition to a new IRB begins, the facility must designate the new IRB(s) under the facility's FWA.

(b) Membership rosters for the new IRB(s) are to be updated as necessary to provide adequate representation of the VA facility for which the IRB(s) review research and to satisfy the requirements of present VHA policy.

(c) The previously designated IRB(s) are not to be removed from the FWA until the transition has been completely effected.

(d) Existing MOUs and SOPs need to be amended as practicable to effect the transition in an orderly fashion and without interruption of IRB oversight.

(e) New MOUs and SOPs are to be developed to reflect the new IRB review arrangements.

(f) During the transition period, the new IRB must review and approve any research projects for which it will assume oversight responsibility. The new IRB may require modifications in the research, to take effect upon assumption of oversight by the new IRB, as a condition for accepting this responsibility.

(g) Once the new IRB and the facility's R&D Committee have formally accepted transfer of oversight to the new IRB, the facility's FWA is to be modified to remove designation of the old IRB(s).

3.1.8 Substantive MOU Changes. Any substantive change in an MOU with an affiliate institution or other entity related to the designation of IRB(s) or other human research protection arrangements must be reported to ORO Central Office within 5 business days.

(a) Any changes to the MOU should be reviewed by the appropriate ORO Central Office Program Official prior to obtaining signatures and initiation.

(b) A copy of the final signed version of the MOU should be forwarded to the appropriate ORO Central Office Program Official.

3.1.9 Accreditation Problems. Failure of the VA facility to achieve the accreditation status required by ORD for human research protections, any change in the facility's accreditation status, or any change in the accreditation status of an affiliate involved in the facility's human research protection program.

(a) Failure of the VA facility to achieve "full accreditation" status from the VA human research accreditation organization, any change in the facility's accreditation status, or any change in the accreditation status of an affiliate involved in the facility's human research protection program will be reported.

(b) Accreditation problems will be reported by the facility Director in writing to ORO Central Office with copies to ORO SRO and the VISN Director within 5 days of being informed of the event.

3.2 Animal Research

3.2.1 Unanticipated Incidents. Any unanticipated incident that seriously affects the health or safety of laboratory animals, including any theft or escape of animals must be reported in writing by the facility Director to ORO SRO (copy to VISN Director) within 5 days of learning of the event.

3.2.2 Unanticipated Loss of Animal Life. Any unanticipated loss of animal life, including loss due to physical plant deficiencies or engineering failures or mishaps must be reported in writing by the facility Director to ORO SRO (copy to VISN Director) within 5 days of learning of the event.

3.2.3 Work-Related and Other Injuries. Any work-related injury to personnel involved in animal research, or any research-related injury to any other person, that requires more than minor medical intervention or leads to serious complications or death, must be reported in writing by the facility Director to ORO SRO (copy to VISN Director) within 5 days of learning of the event.

3.2.4 Reportable Incidents Under Applicable Federal Standards. Any Incident reportable under applicable Federal standards, including but not limited to VHA Handbooks on laboratory animal welfare and research safety, NIH OLAW requirements, the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, the Guide for the Care and Use of Laboratory Animals, and United States Department of Agriculture (USDA) Animal Welfare Act Regulations (UAWAR), members of the VA research community are required to ensure that the incident has been reported in writing to the IACUC. Examples include but are not limited to: (1) Any finding of noncompliance with animal research requirements by any VA office (other than ORO) or any other Federal or state entity (e.g. USDA, OLAW). Subsequent reports to ORO based on findings made by entities external to the facility must include a copy of the official findings. (2) Initiation of VA animal research without written notification from the ACOS for Research that the project may begin. (3) Conduct of VA animal procedures without approval by the IACUC. (Note: Additional examples can be found in VHA Handbook 1058.01) Reports will be made in writing by the facility Director to ORO SRO (copy to VISN Director) within 5 days of learning of the event.

3.2.5 Suspensions or Terminations. Suspensions or terminations of ongoing animal research activities related to concerns regarding the safety or welfare of laboratory animals or the safety, rights, or welfare of research staff or others, or due to operational problems that necessitate a voluntary or involuntary interruption in the conduct of animal research, must be reported.

(a) Such operational problems include the unanticipated resignation of an individual essential to the program (e.g., Veterinary Medical Officer or Veterinary Medical Unit Supervisor), a disease outbreak that threatens colony health, or physical plant issues that must be addressed to remain in

compliance with VA or other Federal requirements must be reported.

(b) Such suspensions or terminations are to be reported whether they impact a specific study or the entire program.

(1) Any suspension or termination of research (e.g., by the IACUC or other research review committee, or by the ACOS for Research or other facility official) must be reported directly (without intermediaries) to the facility Director within 5 business days after the suspension or termination occurs.

(2) The report must be made in writing with simultaneous copies, as applicable, to the ACOS for Research, the R&D Committee, the IACUC, and any other relevant research review committee.

(3) The facility Director must report the termination or suspension to the appropriate ORO RO within 5 business days after receiving such notification.

(4) Suspensions or terminations of animal research are to be reported to the appropriate ORO RO whether they impact a specific study or the entire program.

3.2.6 New MOU or Substantive MOU Changes. The implementation of any new MOU, or any substantive change in an existing MOU, with an affiliate institution (or other entity) related to laboratory animal welfare or animal care and use arrangements.

(a) The facility Director must report the above research event to ORO Central Office, with a simultaneous copy to the ORO SRO, within 5 business days after being informed.

3.2.7 Accreditation Problems. Failure of the VA facility to achieve the accreditation status required by ORD for animal care and use programs, any change in the facility's accreditation status, or any change in the accreditation status of an affiliate involved in the facility's animal care and use program.

(a) The facility Director must report the above research event to ORO Central Office, with a simultaneous copy to the ORO SRO, within 5 business days after being informed.

3.3 Research Safety

3.3.1 Member of the VA Research Community must report the following issues to the Subcommittee on Research Safety (SRS) within 5 days of becoming aware of the event:

(a) Any apparent work-related injury to VA research personnel.

(b) Any apparent work-related exposure of VA research personnel (or apparent research-related exposure of any other person) to hazardous, toxic, or infectious materials at greater than routine levels (i.e., Permissible Exposure Limits or Infection Threshold) or any exposure or injury that requires more than minor medical intervention (i.e., basic first aid), requires extended surveillance of the affected individual(s), or leads to serious complications or death.

(c) Any incident reportable under applicable Federal standards, including but not limited to VHA Handbooks on research safety, NIH OBA guidelines, Occupational Safety and Health Administration requirements, CDC requirements, Department of Transportation requirements, and Nuclear Regulatory Commission (NRC) requirements, members of the VA research community are required to ensure that the incident has been reported in writing to the SRS.

3.3.2 The SRS will review the reported event(s) at its next convened meeting. If the SRS determines that a reportable event has occurred, the SRS Chair must report the determination directly to the Medical Center Director in writing within 5 business days with simultaneous copies to the ACOS/R&D, R&D Chair and any other relevant subcommittee or office with purview over the research.

3.3.3 The Medical Center Director must report the SRS determination to the ORO SRO office within 5 business days of being notified. The report will be made in writing with simultaneous copies to the VISN Director and ORD.

3.3.4 An initial report of an SRS determination is required regardless of whether the determination is preliminary and still under review or final disposition of the matter has been resolved at the time of the report. The SRS must reach a determination that a reportable event did (or did not) occur within 30-45 days after receiving a relevant report. Remedial actions involving a specific study or research team must be completed within 90-120 days of the SRS's determination. Remedial actions involving programmatic noncompliance must be completed within 120-180 days after the SRS's determination, unless remediation requires substantial renovation, fiscal expenditure, legal negotiation, etc.

3.3.5 Any suspension or termination of research (e.g., by the SRS or other research review committee, or by the ACOS for Research or other facility official) related to concerns about research safety must be reported directly by the Chair of the SRS to the facility Director within 5 business days after the suspension or termination occurs.

(a) The report must be made in writing with simultaneous copies, as applicable, to the ACOS for Research, R&D Committee, the SRS, and any other relevant research review committee.

(b) The facility Director will report such suspensions or terminations of research to the ORO SRO within 5 business days after being notified.

(1) The facility Director's written report is required regardless of whether disposition of the event has been resolved at the time of the report.

(2) Follow-up reports detailing any additional findings and appropriate remedial actions must be provided to the relevant ORO regional office at intervals and in a manner specified by that office.

(3) Copies of any ORO compliance reports regarding the research program must be reported to the associate chief of staff for research, Research and Development Committee, any relevant research review committee(s), and the research compliance officer in a timely fashion.

3.3.6 Laboratory Decommissions. The PI or Laboratory Director must obtain authorization (i.e., permission) from the SRS and the ACOS for Research prior to reassigning, vacating, converting to non-laboratory use, or otherwise decommissioning existing laboratory space that requires identification and disposal of hazardous materials, infectious agents, or equipment between uses.

(a) The request for authorization to decommission laboratory space must be made in writing at least 1 month prior to implementation. Upon receiving such a request, the ACOS for Research must notify the affiliate University Occupation Health and Safety Office to coordinate inventory and removal of hazardous materials and infectious agents. Arrangements for decontamination of, or removal or relocation of VA equipment must also be made in writing to the ACOS/R&D.

(b) Within 5 business days of discovering, receiving a credible report of, or otherwise becoming aware of any decommissioning implemented without the required authorization, the ACOS for Research must report the incident directly (without intermediaries) to the facility Director and the VISN Safety Office.

(c) The facility Director must report in writing any unauthorized decommissioning to ORO SRO within 5 business days after being notified.

3.4 Research Laboratory Security Incident Reporting: Within 5 business days of becoming aware of any situation described below, members of the VA research community are required to ensure that the situation has been reported in writing to the ACOS for Research:

3.4.1 Physical Security Problems. Any break-in, physical security breach, or other physical security problem affecting VA research that involves any of following:

- (a) Injury or harm to a human individual or laboratory animal
- (b) A Biosafety Level 3 (BSL-3) research laboratory.
- (c) Loss of any quantity of a select agent or toxin.
- (d) Loss of any quantity of a highly hazardous agent.
- (e) Substantial damage to the facility.
- (f) Substantial loss of equipment, physical resources, or research animals.

3.4.2 Findings of Noncompliance. Any findings of noncompliance related to research laboratory security by any VA office (other than ORO) or any Federal or state entity (e.g., Department of Homeland Security). Subsequent reports to ORO based on findings made by entities external to the facility must include a copy of the official findings.

3.4.3 Other Deficiencies. Any other deficiency that substantively compromises the effectiveness of the facility's research laboratory security program.

3.4.4 Suspensions or Terminations. Any suspension or termination of research (e.g., by the ACOS for Research or other facility official) related to concerns about research laboratory security.

3.4.5 Reports to the Facility Director and ORO ROs. Within 5 business days of discovering, receiving a credible report of, or otherwise becoming aware of any situation described above, the ACOS for Research must report the incident directly (without intermediaries) in writing to the facility Director.

(a) The report must be made in writing with simultaneous copies to the R&D Committee, any relevant research review committee, and the VA Police Service.

(b) Within 5 business days of being notified of them, the facility Director must report the research laboratory security incidents listed above to the ORO SRO.

(1) The facility Director's written report is required regardless of whether disposition of the event has been resolved at the time of the report.

(2) Follow-up reports detailing any additional findings and appropriate remedial actions must be provided to the relevant ORO regional office at intervals and in a manner specified by that office.

(3) Copies of any ORO compliance reports regarding the research program must be reported to the associate chief of staff for research, Research and Development Committee, any relevant research review committee(s), and the research compliance officer in a timely fashion.

3.4.6 Reports to ORO Central Office. Within 5 business days after being informed of any substantive change in an MOU with an affiliate institution or other entity regarding research laboratory security arrangements, the facility Director must report the change to ORO Central Office, with a simultaneous copy to the ORO SRO.

3.5 Research Information Protection Program Incidents.

3.5.1 Unauthorized access, use, disclosure, transmission, theft, or loss related to research of VA Sensitive Information including personal health information, individually identifiable private information, or confidential information, by the Privacy Act, HIPAA, or by Federal records requirements.

3.5.2 Any research-related incidents reportable to NSOC.

(a) Report to ACOS for Research, PO, and ISO required within one hour.

(b) The facility Director must report the above research event to the ORO RO within 5 business days after being informed.

(c) Findings of noncompliance.

(d) Any other deficiency that substantively compromises the effectiveness of the facility's research information protection program.

(e) Suspensions of terminations of research related to information protection concerns.

(1) Report to ACOS for Research, PO, and ISO required within five business days.

(2) The facility Director must report the above research event to the ORO RO within 5 business days after being informed.

(3) The facility Director's written report is required regardless of whether disposition of the event has been resolved at the time of the report.

(4) Follow-up reports detailing any additional findings and appropriate remedial actions must be provided to the relevant ORO regional office at intervals and in a manner specified by that office.

(5) Copies of any ORO compliance reports regarding the research program must be reported to the associate chief of staff for research, Research and Development Committee, any relevant research review committee(s), and the research compliance officer in a timely fashion.

3.1.18 Research Misconduct. ORO Central Office must be notified as soon as possible (preferably by telephone or email) of any allegation of research misconduct. Subsequent written notification must be provided as specified by ORO Central Office.

4.0 RESPONSIBILITIES

4.1 Investigators, the Research Compliance Officer and other members of the VA research community must report research events listed in this SOP to the ACOS/R&D and the appropriate committee or subcommittee(s). The ACOS/R&D or committee/subcommittee chairperson must report the event(s) to the Facility Director and the R&D Committee as soon as possible but no later than 5 business days after being informed.

4.2 The facility Director must report research events listed in this SOP within 5 days of learning of the event to the ORO SRO with a simultaneous copy to the VISN Director. Reports should be made via encrypted email.

4.3 Contents of Initial Reports to ORO. Initial reports to ORO of reportable research events must (as applicable) include:

- (a) The name and any relevant Assurance number of the reporting VA facility.
- (b) The title of the research project(s).
- (c) The number(s) used by the facility's Research Service or relevant research review committee(s) to identify the project(s).
- (d) The name of any external sponsor(s) of the project(s).
- (e) The funding source(s) for the project(s).
- (f) The name of any agencies or organizations external to VA that were notified, or need to be notified, of the event.
- (g) A description of the event being reported.
- (h) A description of any immediate actions taken to address or investigate the reported event.

4.4 Contents of Follow-Up Reports to ORO. After the initial report, additional investigation and review are frequently needed to obtain a complete understanding of the facts associated with the case. Interim and final reports must be provided as directed by ORO to incorporate the full scope of relevant determinations and remedial actions, including programmatic actions as warranted.

4.5 Implementation of Remedial Actions. The relevant research review committee is responsible for determining the appropriate remedial action(s) in response to identified noncompliance and for verifying that the remediation is implemented as required.

(a) Except in extraordinary circumstances, remedial actions related to specific research projects must be completed within 90-120 days of the research review committee's determination of noncompliance (or of such a determination by ORO).

(b) Except where remediation requires substantial renovation, fiscal expenditure, hiring, legal negotiations, or other extenuating circumstances, remedial actions related to programmatic noncompliance must be completed within 120-180 days of the noncompliance determination.

(c) Where completion of remedial actions extends beyond the periods described in the preceding subparagraphs, the facility must provide ORO with a written justification for the delay and an acceptable timeline for completion. 4) Initial the completed report and facilitate its submission to the Director of the ORO SRO that oversees the VHA facility. A copy of all relevant Committee minutes from meetings in which the event in research and subsequent actions were discussed, ratified, or summarized needs to accompany the report to the ORO, or be sent when the IRB minutes become available, but in no case no later than 4 weeks after the committee meeting.


Shelley K. Coleman
Acting Research Compliance Officer